Docket No.: 31894-199297
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Zemel et al.

Application No: 10/827,353

Confirmation No: 2617

Filed: April 20, 2007

For: HIGH CALCIUM FOODSTUFFS FOR WEIGHT LOSS

Art Unit: 1616

Examiner: E.J. Webman

Atty. Docket No: 31894-199297

Customer No:
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PATENT TRADEMARK OFFICE

DECLARATION OF DR. MICHAEL B. ZEMEL UNDER 37 C.F.R § 1.132

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Sir:

I, Michael B. Zemel, Ph.D., declare the following, based on my own knowledge, information, and belief.

1. I am an inventor of subject matter described and claimed in the above-identified U.S. Patent Application. Highlights from my resume (Attachment A) are as follows. I am currently employed as the Director of the Nutrition Institute since 1994 and Professor of both Nutrition and Medicine since 1990, at the University of Tennessee, Knoxville, Tennessee. I earned my B.S., M.S. and Ph.D. in Nutritional Sciences at the University of Wisconsin, Madison, Wisconsin.

2. I have conducted, and continue to conduct, sponsored research for Dairy Management, Inc., licensee of the pending application.

3. I have authored over 150 refereed publications primarily describing investigations of the role of cell calcium regulation in obesity, insulin resistance and hypertension. My work focuses on obesity genetics, the regulation of human adipocyte lipogenesis and lipolysis via calcium-linked mechanisms, and modulation of obesity by dietary calcium and dairy products. Other professional work experience includes Research Biochemist/ Endocrinologist, VA Medical Center, Allen Park, MI 1987-1991; Associate Professor of Endocrinology, Wayne State University, Detroit, MI, 1985-1990; and Assistant/Associate Professor of Nutrition and Food Science, Wayne State University, Detroit, MI, 1980-1990.

4. I am familiar with the referenced application and the pending claims.

5. As originally filed, the above-referenced application describes the effect of dietary administration of calcium and/or dairy in increasing the metabolic consumption of adipose tissue, inducing weight loss, reducing weight gain, increasing fat loss, and/or reducing fat gain, without regard to gender.

6. As described in Example 2, mice that exhibited diet-induced obesity were randomly assigned to five groups. One group was continued ad lib on a low calcium (0.4%) diet with no modification, while the other four groups were maintained with energy restriction (70% of ad lib). The mice in basal restriction group were placed on the basal low calcium (0.4%) diet with Kcal-restriction. A high calcium energy restricted group received the basal diet supplemented with calcium increased to 1.2%. Two additional groups, termed medium dairy and high dairy, were fed modified basal diet in which either 25 or 50% of protein was replaced by non-fat dry milk, with total dietary calcium increasing to 1.2 or 2.4%,

respectively. Energy restriction resulted in a body weight loss by 11% compared to ad lib group. However, markedly greater weight reductions of 19, 25 and 29% were observed in the high calcium, medium and high dairy groups, respectively.

7. In humans, including men and women, the patent application teaches that above suboptimal amounts, e.g., 773 or 1346 mg/day of calcium and/or 57 or 102 servings of dairy/month were correlated with increasing the metabolic consumption of adipose tissue, inducing weight loss, reducing weight gain, increasing fat loss, and/or reducing fat gain.

8. This metabolic effect holds true without limitation as to gender. Further research that a calorie-restricted diet containing suboptimal amounts of dietary calcium and/or dairy, as taught by the specification, is effective for increasing the metabolic consumption of adipose tissue, inducing weight loss, reducing weight gain, increasing fat loss, and/or reducing fat gain in both men and women, without limitation as to gender. See two articles submitted herewith, Zemel, et al., "Dairy augmentation of total and central fat loss in obese subjects," International Journal of Obesity (2005) 1-7, and Zemel, et al., "Effects of Calcium and Dairy on Body Composition and Weight Loss in African-American Adults," Obesity Research Vol. 13, No. 7, July 2005.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 26th day of June, 2007

Michael B. Zemel, Ph.D.

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